

PATENT COOPERATION TREATY

REC'D 25 OCT 2004

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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|---|---|--------------------|---|---|
| Applicant's or agent's file reference 14364-0094 | | FOR FURTHER ACTION | | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/US03/18270 | International filing date (day/month/year) 11 June 2003 (11.06.2003) | | Priority date (day/month/year) 02 August 2002 (02.08.2002) | |
| International Patent Classification (IPC) or national classification and IPC IPC(7): B05D 3/00, 3/10, 7/14; A61L 27/00, 27/28, 27/54, 31/00, 31/16, 33/00 and US Cl.: 427/2.1, 2.24, 2.25, 299, 301, 322, 327, 337407.1, 409 | | | | |
| Applicant | | | | |
| THE GOVERNMENT OF THE UNITED STATES OF AMERICA | | | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of — sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

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| Date of submission of the demand | Date of completion of this report |
| 02 March 2004 (02.03.2004) | 04 October 2004 (04.10.2004) |
| Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | Authorized officer Shrive Beck  Sean Proctor Paralegal Specialist Telephone No. 571-272-1700 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/18270

I. Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed. the description:pages 1-32 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____. the claims:pages 33-39, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____. the drawings:pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____. the sequence listing part of the description:pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig NONE5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/18270

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

| | | |
|-------------------------------|---|-----|
| Novelty (N) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |
| Inventive Step (IS) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |
| Industrial Applicability (IA) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-5, 8-10, 18, 22-23, 26, 32-34, 36, 40-41, and 43 lack novelty under PCT Article 33(2) as being anticipated by Fitzhugh et al. (US 2001/0041184 A1). Fitzhugh et al. teach coating a substrate with an amine-functionalized silane, cross-linking, and then coating with a nitric-oxide-releasing functional group (abstract; P24-25). The substrate of Fitzhugh et al. may be a metal such as stainless steel (P23). Fitzhugh et al. teach that treatment of polymer substrates, such as PTFE or other rubbers, in this manner is known, while less desirable (P15; P34). Fitzhugh et al. teach diazeniumdiolate nitric-oxide releasing functional groups for attachment to the amine-functionalized silane (P24). In addition to the above steps, Fitzhugh et al. teach the use of a nucleophilic residue for contact with the amine-functionalized silane (P27) and/or with polymer topcoats. Fitzhugh et al.'s method would create the device of claims 32-34, for example arterial stents (P23).

Claims 6-7, 11-17, 19-21, 24-25, 27-31, 35, 37-39, and 42 lack an inventive step under PCT Article 33(3) as being obvious over Fitzhugh et al. Fitzhugh teaches that which is disclosed above, but fails to teach a glass or ceramic substrate. However, Fitzhugh teaches a variety of medical substrates, which are known in the art to often be made of glass or ceramic. It would have been obvious to an ordinary artisan to coat glass or ceramic substrates using the method of Fitzhugh. Fitzhugh teaches the use of polymer substrates, amine-functionalized silanes for coating said substrates, and cross-linking agents which would be inclusive of the specific polymers, silanes, and crosslinking agents required by Applicant in dependent claims. Regarding the requirement to repeat contact with the nucleophilic residue taught above, Examiner notes that the broad concept of repeating process steps would have been obvious to an ordinary artisan to build up a coating thickness. Fitzhugh teaches the use of drugs as the nucleophile topcoat part of the coating. Heparin is a commonly used drug for coating stents and would have been immediately apparent to one of ordinary skill in the art as a suitable drug in the method of Fitzhugh.

Claims 1-43 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/18270

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 6,7,11-17,19-21,24,25,27-31,35,37-39 and 42
The opinion as to Novelty was negative (No) with respect to claims 1-5, 8-10, 18, 22-23, 26, 32-34, 36, 40-41, and 43
The opinion as to Inventive Step was positive (Yes) with respect to claims NONE
The opinion as to Inventive Step was negative (NO) with respect to claims 1-43
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-43
The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE